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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,519	05/01/2001	Ralf M. Luche	200125.422	4032

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1652	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/847,519	Applicant(s) Luche et al.
	Examiner Nashaat T. Nashed	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 12, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above, claim(s) *1 and 15-49* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I	Claims 1, drawn to a polypeptide, classified in Class 435, subclass 195.
Group II	Claims 2-14, drawn to a polynucleotide, vector and host cell comprising said polynucleotide, and a recombinant method to produce polypeptide, classified in Class 435, subclass 195, and Class 536, subclass 23.2.
Group III	Claims 15-21, drawn to antibody and method of use, classified in Class 530, subclass 387.1.
Group IV	Claims 22-25, drawn to a hybridization method to detect polynucleotide, classified in Class 435, subclass 6.
Group V	Claims 26-32 and 46-49, drawn to a method of identifying an agent that modulate the activity of a polypeptide, classified in Class 435, subclass 18.
Group VI	Claims 33-42 and 24-33, drawn to a method of modulating proliferative response in a cell, classified in Class 424, subclass 94.6.
Group VII	Claims 43-44, drawn to 10 different methods for treating 10 different diseases, classified in Class 424, subclass 94.6.
Group VIII	Claims 45, drawn to a mutant DSP-14 polypeptide, classified in Class 435, subclass 195.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group I, the polynucleotide of Group II , the antibody of Group III, and the mutant DSR-14 polypeptide of Group VIII are independent chemical entities and require different literature searches in the patent and non-patent literature. Claims drawn to method of making the enzyme using the recombinant polynucleotide are placed with the polynucleotide sequence of Group II because, although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search them in addition to the DNA sequences.

The polypeptides of Groups I and VIII, the hybridization method of Group IV, the method of modulating a proliferative response in a cell of group VI, and the method of treatment of Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the polypeptides of Groups I and VIII are not used in any of the methods of Groups IV, VI, and VII.

The polypeptide of Group I and the method of identifying modulator for the polypeptide are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group I can be utilized in other methods such as in a method to make of making antibodies.

The mutant polypeptide of Groups VIII and the of Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the mutant polypeptide of Group VIII is not used in the method of Group V.

The polynucleotide of Group II and the methods of Groups IV and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group II can be utilized in other methods such as in a recombinant method to make ta polypeptide.

The polynucleotide of Group II and the methods of Groups VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the polypeptide of Group II is not used in any of the methods of Groups VI, and VII.

The antibody of Groups III and the methods of Groups IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibody of Group III is not used in any of the methods of Groups IV, V, VI, and VII.

The methods of Groups VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different methods are independent methods used for different purposes.

The methods of Groups IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are independent methods having different steps, used for different purposes, and have different product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Stephen J. Rosenman on February 7, 2002 a provisional election was made without traverse to prosecute the invention of Group II, claims 2-14. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1, 15-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The application has been amended as requested in the communication filed December 12, 2001.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim 6 is objected to because it is dependent on a claim drawn to non-elected subject matter. For examination purposes only, all the embodiment of claim 1 has been incorporated in claim 6. Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicant discloses the nucleic acid sequences (SEQ ID NO: 1) encoding the amino acid sequence of SEQ ID NO: 2. The polypeptide of SEQ ID NO: 2 is sought to be a dual specificity phosphatase which, at best, is a generic asserted utility. Although applicants point to the fact that there is no consensus sequence among all dual specificity phosphatases, they have identify the protein of SEQ ID NO: 2 as dual specificity phosphatases based on the identification of a conserved sequence among dual specificity phosphatases. No other evidence in the specification to support the contention that the protein of SEQ ID NO: 2 is a dual specificity phosphatase or any role in biological activity

such as regulating one or more MAP-kinase. Evidence in the prior art suggests that the protein could have other enzymatic activities such as phospholipase taught by Acton (U. S. Patent 6,268,135), protein tyrosine phosphatase (Acton, U. S. Patent 6,285,582) and the phosphatase of SEQ ID NO: 4 disclosed in U. S. Patent 6,132,964. The previously mentioned patent has identifies a protein having either an identical or highly homologous to residues 152-163 of SEQ ID NO: 2, the putative active site domain. The phospholipase of SEQ ID NO: 2 of U. S. patent 6,268,135 (135) is overall 40% homologous to SEQ ID NO: 2 of the instant application. Residues 133-166 of SEQ ID NO: 2 of the patent has a much higher sequence homology to the putative active site domain of SEQ ID NO: 2 of the instant application corresponding to residues 143-175, 24 identical residues, 7 conservative, 1 mismatch, and no insertion or deletion. Yet, the two sequences are claimed to have different utility and function. Ths examples cited above clearly indicate that: (i) sequence homology in general does not impart chemical or biological function; and (ii) even the generic utility identified in the specification is in doubt and therefore, the protein disclosed in the instant application has no credible utility. In addition to the doubt about the generic utility, dual specificity phosphatases belong to a family of enzymes which catalyze the hydrolyses of many phosphorylated proteins. Each member of the family is expected to have different specific substrate having different structure and functions, and its action on that specific substrate is expected to have a specific biological consequences. The specification does not disclose a specific function of the polypeptide of SEQ ID NO: 2, its relationship to any disease, or any specific real world use. The specification describes a possible generic function for the protein, nucleic acid, and antibodies. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantlly make the polypeptide of SEQ ID NO: 2 which neither the gene or the polypeptide associated with any specific credible use or a disease. The mere fact that the polypeptide disclosed in the specification are called DSP-14 which stand for Dual Specificity Phosphates-14 is indicative that the applicants have no idea about the specific function of this protein at the time they filed their application. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no generic, specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 2-5 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2 and 3 are directed to all possible polynucleotide sequence encoding at least 10 or 15 contiguous amino acid residues of SEQ ID NO: 2. Claim 11 is drawn to a nucleic acid that hybridized to the nucleic acid sequence under intermediate to low stringency conditions. The specification, however, only provides a single representative species from human encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these DNAs by any identifying structural characteristics or properties other than the activities recited in claim 6, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 4, 5, 12, and 13 are included in this rejection because they are dependent on a rejected claim and do not cure its deficiencies. Since the claims include a structure feature, adding a functional language such as dual phosphatase activity would vacate this rejection.

Claims 2-14 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for any claims. The specification does not enable any person skilled in the art to make and use the invention. The claims are broader than the enablement provided by the disclosure with regard to the lack of utility for the disclosed nucleic and amino acid sequences of SEQ ID NO's: 1 and 2, and all possible nucleic acid sequences encoding 50% sequence identity to SEQ ID NO: 2. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation

necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses all the nucleic acid sequences encoding a polypeptide having 50% sequence identity to SEQ ID NO: 2 including insertion, deletion, substitution and combination thereof mutant. The specification provides guidance and examples in the form of an assay to isolate the nucleic acid sequence of SEQ ID NO: 1 which encodes the amino acid sequence of SEQ ID NO: 2. The specification does not provide a credible utility. While molecular biological techniques and genetic manipulation to make and use the constructs claimed are known in the prior art and the skill of the artisan are well developed, knowledge regarding the enzymatic, functional and biological activity of the polypeptide of SEQ ID NO: 2 and its use is lacking. Thus, searching for an analog of the polypeptide of SEQ ID NO: 2 having 50% sequence homology and having any desired function is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify such a protein and its function is enormous. Since routine experimentation in the art does not include screening genomic and cDNA from any biological source as well as man-made DNA libraries for a nucleic acid sequence encoding dual phosphatase activity where the expectation of obtaining a desired protein or functionality is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding re-engineering the protein of SEQ ID NO: 2 to a desired structure and function, the biological source of the desired protein with a desired function, the nucleic and amino acid sequence homologies of a protein having the function of SEQ ID NO: 2 and the biological and chemical function of the protein of SEQ ID NO: 2. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim 10 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to 15 contiguous nucleotide of a nucleic acid encoding a protein which is 50% homologous to SEQ ID NO: 2. Thus, there is embodiments of claim 6 which has drawn to a nucleic acid sequence with no structure or function disclosed.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

> subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 2 is rejected under 35 U.S.C. § 103 as being unpatentable over U. S. patent 6,258,582 (Acton).

Acton teaches the nucleic acid sequence of SEQ ID NO: 4 encoding a protein tyrosine phosphatase of SEQ ID NO: 5 which comprises the active site domain having the amino acid sequence VXVHCXAGXSRSXTXXXAYLM wherein X is any amino acid residues, column 12, paragraph 3. Residues 114-124 of SEQ ID NO: 5 of the patent are SRSATLVLAYLM are identical to residues 152-163 of SEQ ID NO: 2 of the instant invention. Since Acton teaches those 12 amino acid are conserved sequence among all phosphatases, one of ordinary skill in the art would have been motivated to prepare a nucleic acid sequence encoding said 12 amino acid residue to use it as probe to screen for phosphatases in a human and other organism genomic or cDNA libraries. It should be noted that phosphatases including phospholipases are useful enzymes having many uses including dephohorelation of proteins and phospholipids. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is

(703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner